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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,546	05/02/2002	Dan L. Eaton	P3230R1C001-168	1060
30313 7590 04/19/2007 KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET IRVINE, CA 92614			EXAMINER DUFFY, PATRICIA ANN	
			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/063,546

Applicant(s)

EATON ET AL.

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### RESPONSE TO AMENDMENT

The amendment and response filed 3-22-07 have been entered into the record. Claims 1-5 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

#### *Rejections Withdrawn*

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claim.

#### *Rejections Maintained*

Claims 1-5 stand rejected under 35 U.S.C. 102(a) as being anticipated by Barnes (WO 00/18904, published 06 April 2000) for reasons made of record.

Applicants' arguments have been carefully considered but are not persuasive. Applicants reiterate the teachings of inherency and that the antibodies of the prior art necessarily do not bind the polypeptide of SEQ ID NO:38. This is not persuasive, it is well established in the art that an antibody binds to a minimal protein epitope of 6 consecutive amino acids. The polypeptide of the prior art and the instant polypeptide set forth in SEQ ID NO:38 have 91% identity over 720 consecutive amino acids and 100% over at least 400 consecutive amino acids. Since the polypeptides would necessarily share antibody epitopes in common the antibodies of the prior art would necessarily bind the polypeptide of SEQ ID NO:38. Applicants argue Li and Lederman et al to establish that changing one amino acid can change binding specificity of a monoclonal antibody and that some antibodies may bind regions that are different. This is not persuasive because the claims clearly encompass monoclonal antibodies that bind the regions that are identical and the claims are not limited to or directed to the regions that are different as argued. The

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argument that there may be regions that distinguish the two polypeptides, does not obviate the fact that there are more regions that will not distinguish the polypeptides and the claims encompass both of these. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the antibodies of the prior art does not possess the same functional characteristics of the claimed antibodies). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Applicants also argue the "Stempel Doctrine" and insist that a showing under 37 CFR 1.131 is not needed to demonstrate that Applicants had the invention prior to the cited relevant art and argue that the provisional document establishes possession of the invention prior to the date of the 102(a) cited art. This is not persuasive because as of 10-26-06 the amendment to the specification changed the claim for priority to delete the relevant provisional documents. *The priority claim to the relevant and argued provisional document has been deleted.* As such, Applicants cannot rely upon an unclaimed priority in combination with the "Stempel Doctrine" to establish constructive reduction to practice prior to the date of the cited art. Further, Applicants argue possession of the polypeptide of SEQ ID NO:38, wherein the claims and art at issue are directed to antibodies *per se*. As such, possession of SEQ ID NO:38 does not establish constructive reduction to practice or conception of the now claimed antibodies in the provisional document. Applicants reliance on *In re Moore* and "The Stempel Doctrine" is therefore misplaced.

#### *Status of Claims*

Claims 1-5 stand rejected.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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*Patricia A. Duffy*  
Patricia A. Duffy

Primary Examiner

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